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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,211	04/09/2001	Hideshi Fujiwake	P107331-00009	3660

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,211

Applicant(s)

Fujiwake et al.

Examiner

Joyce Tung

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 24, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/2003 has been entered.
2. The amendment filed 4/24/2003 has been entered. Following the entry of the amendment, claims 1-6 are pending.
3. Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

- 4 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5 Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Claims 1-6 are vague and indefinite because it is unclear whether or not a plurality of differently labeled oligonucleotides is used to detect multiple mutations on a single nucleic acid sequence. Clarification is required.
- b. Claim 6 is vague and indefinite because it is unclear as to the phrase "a single PCR step". It can not be determined whether or not there is only one cycle of PCR reaction. Clarification is required.
6. The claims 1-6 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gjerde et al. (6,210,885, issued 4/3/2001).

Gjerde et al. disclose a method of detecting mutation in a sample via Denaturing Matched Ion Polynucleotide Chromatography (DMIPC) and the invention is to increase to improve mutation detection in ds DNA by DMIPC (See column 6, lines 51-54). The method includes

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covalently attaching a chemical tag to the sample DNA or a corresponding wild type fragment to form a tagged polynucleotide, hybridizing the sample DNA with the corresponding wild type fragment to form a mixture of homoduplexes and heteroduplexes if a mutation is present in the sample DNA fragment and applying the products to a separation medium, eluting at least the denatured heteroduplexes and therefore separating the heteroduplexes from homoduplexes and then detecting the tagged polynucleotide (See column 9, lines 9-34). The invention is also applied to multiplex mutation analysis (See column 28, lines 59-67) in which mixtures of dsDNA are tagged with different fluorescent dyes which are uniquely detectable from each other. So it can be used in "multiplex" applications to detect each component of a mixture independently of the other components of the mixture simultaneously (See column 28, lines 9-17). The invention applies four primers which are differentially labeled. Four different regions of a template are amplified simultaneously. The four expected PCR products are monitored simultaneously on MIPC column (See column 28, lines 34-42 and lines 59-67). The invention further provides a method for increasing the melting temperature to detect mutation by DMIPC (See column 32, lines 16-46).

Gjerde et al. do not disclose a method to detect a plurality of mutation sites on a single nucleic acid fragment with a plurality of differently labeled oligonucleotides of varying types, and before the bonding, an amplification step is included.

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the method of Gjerde et al. to detect a plurality of mutation sites on a single

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nucleic acid fragment by using ion pairing reverse phase chromatography with a plurality of differently labeled oligonucleotides of varying types. Gjerde et al. disclose that the invention is used to detect multiplex mutations in a DNA sample via DMIPC in which a plurality of primers (four primers) differentially labeled and four different regions of the template are amplified simultaneously (See column 28, lines 28-47). So the four primers labeled with fluorescence act like probe to detect a plurality of mutation sites on a single DNA fragment. In addition, the method of Gjerde et al. is an improvement to detect mutations in dsDNA by DMIPC Therefore, it would have been prima facie obvious for an ordinary skill in the art to apply the method of Gjerde et al. to detect a plurality of mutations on a single nucleic acid fragment with a plurality of differently labeled oligonucleotides of varying types.

Although the method of Gjerde et al. et al. do not disclose before the bonding, an amplification step is included, amplifying a target nucleic acid fragment to get a desirable amount of the target nucleic acid for increasing the accuracy of the detection was routine practice in the art at the time of the invention Therefore, it would have been prima facie obvious for an ordinary skill in the art to add the amplification step of a target nucleic acid fragment, before applying the method of Gjerde et al. to detect a plurality of mutations on a single nucleic acid fragment.

Summary

9. No claims are allowable.

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10. U.S. patent NO. 6461,819, issued 10/2002 is made of record as references of interests since Gjerde et al. disclose ion pairing reverse phase HPLC effectively which separates mixtures of double stranded polynucleotides (See column 7, lines 31-37) and that the invention provides an improved chromatographic method for determining the presence of one or more mutations in DNA sample (See column 12, lines 42-63).

11. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

July 11, 2003


JEFFREY SIEW
PRIMARY EXAMINER
7/14/03